May 6, 1999

Karen F. Suomi 3494 51st Avenue Circle West Bradenton, FL 34210-3225

1709 '99 MAY 10 P3:31

Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20857-0003

Dear Friends,

After discussing <u>Docket No. 98N-1265</u> with Dr. Stephen Suomi, Chief of Child Health and Human Development at NIH, I feel it necessary to make written comment to you as I believe that in its present form, the MOU, as well as the Compounding Section of 503A of the Modernization Act, SEVERELY restricts the rights of physicians and patients to obtain healthcare products from the provider of their choice, and infringes on the rights of compounding pharmacists to serve the public's medical needs.

If the MOU is approved it will limit the rights of pharmacists to suggest alternatives to physicians and patients. This time-honored patient-physician-pharmacist relationship is jeopardized because the MOU labels this common practice solicitation, if the alternative drug is a compounded drug. In effect, the MOU places a gag order on pharmacists who specialize in compounded drugs.

By limiting the interstate distribution of compounded prescriptions, with no concern for limiting the same distribution practices for noncompounded prescriptions, the MOU threatens the economic survival of SPECIALTY PHARMACIES further restricting consumer choices.

Sincerely, Laren H. Suomi

Karen F. Suomi

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Karen F. Suomi 3494 51st Avenue Circle West Bradenton, FL 34210





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